

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION**

MORTON GROVE)	
PHARMACEUTICALS, INC.)	
)	
Plaintiff,)	
)	No: 08-CV-1384
v.)	
)	Judge Bucklo
THE NATIONAL PEDICULOSIS)	Magistrate Judge Mason
ASSOCIATION, INC.)	
)	
Defendants.)	
)	

**PLAINTIFF’S MEMORANDUM OF LAW IN SUPPORT OF
ITS MOTION TO STRIKE ALLEGATIONS AND DEFENSES
IN DEFENDANT’S ANSWER AND COUNTERCLAIM**

Defendant the National Pediculosis Association, Inc. (“NPA”) asserts numerous defenses and factual allegations against Morton Grove Pharmaceuticals, Inc. (“Morton Grove”) in its Answer and Counterclaim that should be stricken pursuant to Federal Rule of Civil Procedure 12(f). Many of the NPA’s defenses fail to meet the minimal notice pleading standard and only rehash already-rejected arguments. Others are not even affirmative defenses at all. In addition, various factual allegations in the NPA’s counterclaim are immaterial, impertinent, and scandalous, as well as unduly prejudicial. This Court should strike both the NPA’s improper and inadequate defenses, along with the immaterial, impertinent, scandalous, and unduly prejudicial allegations present in the NPA’s counterclaim.

Motions to strike are appropriate in situations where they “remove unnecessary clutter from the case, [because then] they serve to expedite, not delay.” *Heller Fin., Inc. v. Midwhey Powder Co., Inc.*, 883 F.2d 1286, 1294 (7th Cir. 1989); *see* 5C Charles Alan Wright & Arthur R. Miller, *Fed. Practice & Procedure* § 1382. Here, striking the defenses and allegations

described below will substantially expedite the case, as fewer issues will need to be addressed in discovery and material that has no relevance to this case will be removed from these proceedings.

I. THE NPA’S IMPROPER DEFENSES SHOULD BE STRICKEN

As described below, NPA’s defenses 1-22 should be stricken pursuant to Rule 12(f) of the Federal Rules of Civil Procedures, which directs that a court “may strike from a pleading an insufficient defense.” Defenses 2-7, 10-15, and 17 should be stricken because this Court has already ruled on them in substance, and defenses 1, 12-14, and 17-21 should be stricken because they fail to meet the appropriate pleading standards. Further, defenses 1-10, 15-16, and 22 of the NPA’s “Affirmative and Other Defenses” are indeed other defenses, not affirmative defenses at all, and also should be stricken. Courts in this district use a three-part test to examine an affirmative defense: (1) is the matter properly pleaded as an affirmative defense; (2) if so, is it adequately pleaded under the requirements of Rules 8 and 9; and (3) will it stand under a standard identical to Rule 12(b)(6). *Global Poly Inc. v. Fred’s Inc.*, 2004 WL 532844, at *5 (N.D. Ill. Mar. 11, 2004) (App. Tab 1). If a matter does not meet the pleading standards, it will be dismissed without prejudice. *Id.* All of the NPA’s defenses fail this test.

A. NPA’s Defenses 2-7, 10-15, and 17 Have Already Been Deemed Insufficient and Should Be Stricken

The NPA rephrases as defenses several arguments that this Court has already ruled upon and determined inadequate, and these defenses should be stricken. *See DGM Invs., Inc. v. New York Futures Exch., Inc.*, 2004 WL 635743, at *2 (D.C.N.Y. Mar. 31, 2004) (granting motion to strike affirmative defenses because defenses challenged adequacy of complaint, after court had already determined complaint was adequate) (App. Tab 2); *Cohn v. Taco Bell Corp.*, 1995 WL 247996, at *2 (N.D. Ill. Apr. 24, 1995) (striking affirmative defense

that plaintiff did not state a claim, because court had previously rejected defendant's motion to dismiss for failure to state a claim) (App. Tab 3); *Rimac v. Nissan Motor Corp., U.S.A.*, 1985 WL 4868, at *1-2 (N.D. Ill. Dec. 18, 1985) (striking defense concerning jurisdiction, where Court noted it had denied a motion to quash service of summons, and it still believed that ruling was proper) (App. Tab 4).

This Court previously rejected these arguments in connection with the NPA's Rule 12(b)(6) motion to dismiss Morton Grove's complaint in the parties' prior action. (*See* Exhibit A, June 18, 2007 Memorandum Opinion and Order, Docket Entry 86 in Case No. 06-CV-3815.) In that opinion, this Court effectively rejected the arguments that the NPA now reiterates in defenses numbered 2-7 and 10-11. This Court also addressed and rejected the NPA's arguments concerning the First Amendment of the United States Constitution, the Illinois Constitution, malice, and privilege—yet these arguments are re-hashed as defenses numbered 12-15 and 17. This Court should strike all of these defenses as insufficient, so that the parties and the Court do not waste time addressing them again.

B. NPA's Defenses 1-10, 15-16, and 22 Are Not Proper Affirmative Defenses and Should Be Stricken

The NPA's defenses which are only denials are not proper affirmative defenses, and they should be stricken. An affirmative defense is "an admission of the facts alleged in the complaint coupled with an assertion of some other reason as to why defendant is not liable," *Cohn*, 1995 WL 247996, at *3, and simple denials do not qualify, *see Crawford v. Equifax Payment Servs., Inc.*, 1998 WL 704050, at *11 (N.D. Ill. 1998) ("A defense is affirmative only if (1) it is specifically listed in Fed. R. Civ. P. 8(c) or (2) it raises factual or legal issues outside of the plaintiff's prima facie case so the defense cannot be raised through a simple denial in the answer.") (App. Tab 5).

The NPA improperly lists “Affirmative and Other Defenses” together. This is not permitted under Federal Rule of Civil Procedure 8, and the NPA should not be allowed to use this tactic to fill the pleadings with improper defenses. In fact, these “Other Defenses” are only repetitive of the specific denials the NPA included in its Answer—they are repetitive and add no new information to the case. For example, a necessary element of Morton Grove’s Lanham Act claim is that the NPA made “a false statement of fact . . . in a commercial advertisement about its own or another’s product.” *See Hot Wax, Inc. v. Turtle Wax*, 191 F.3d 813, 819 (7th Cir. 1999). Several of the NPA’s defenses only seek to deny that element by asserting that the NPA is not a competitor or that its statements were not about Morton Grove or its products, such as the defenses numbered 3-4 and 7. Likewise, the defenses numbered 1-2, 5-6, 8-10, 15-16, 22 only repeat the NPA’s denials— they are also not proper affirmative defenses.

C. NPA’s Defenses 1, 12-14, and 17-21 Fail to Meet Basic Pleading Standards and Should Be Stricken

The NPA’s defenses that fail to meet the applicable pleading standards should be stricken as insufficient. Defenses are pleadings and thus subject to the pleading requirements in the Federal Rules of Civil Procedure. *Heller Fin., Inc.*, 883 F.2d at 1294. As such, defenses must set forth a “short and plain statement” of the defense. Fed. R. Civ. P. 8(a); *Heller Fin., Inc.*, 883 F.2d at 1294; *see Am. Top English v. Lexicon Mktg. (USA), Inc.*, 2004 WL 2271838, at *11 (N.D. Ill. Oct. 4, 2004) (“Where an affirmative defense is merely listed without a short statement to explain the basis for the defense, it is properly stricken.”) (App. Tab 6). “Bare bones conclusory allegations” are inadequate, *Heller Fin., Inc.*, 883 F.2d at 1295, as are defenses that simply recite a legal standard, *e.g.*, *Surface Shields, Inc. v. Poly-Tak Protection Sys., Inc.*, 213 F.R.D. 307, 308 (N.D. Ill. 2003) (Bucklo, J.) (granting motion to strike defenses that only “rephrase[ed] the standard for evaluating a motion to dismiss under Rule 12(b)(6),” noting that

such allegations do not “add substance to the litigation” but are instead “clutter”). Defendants must plead some basis even for defenses such as laches or statute of limitations. *Global Poly Inc.*, 2004 WL 532844, at *6 (finding pleading of affirmative defense of laches barred because “the pleading fails to put [the party] even on notice of the conduct allegedly constituting . . . laches”); *Surface Shields, Inc.*, 213 F.R.D. at 308 (striking doctrine of laches and statute of limitations affirmative defenses because defendant did not allege specific facts to show how those affirmative defenses might be applicable).

The NPA has included many defenses that fail to meet these notice pleading standards, including the following:

1. Plaintiff cannot state any claim upon which relief can be granted.
12. All of Plaintiff’s claims are barred by the First and Fourteenth Amendments to the United States Constitution.
13. All of Plaintiff’s claims are barred by Article One, Section Four of the Illinois Constitution.
14. All of Plaintiff’s claims are barred because NPA’s statements are protected by qualified and other privileges.
17. Plaintiff’s claims for injunctive or other equitable relief are precluded by the First Amendment.
18. Plaintiff’s claims are barred by the applicable statute of limitations.
19. Plaintiff’s claims are barred by the doctrine of laches.
20. The doctrine of laches precludes Plaintiff from obtaining injunctive or other equitable relief.

None of these statements explain the basis for the defenses they attempt to assert. The first only states the 12(b)(6) standard for a motion to dismiss and sets forth absolutely no explanation for the basis of the defense at all. Defenses numbered 12-13 and 17 fail to give any reason why Morton Grove’s claims might be barred by those constitutional provisions. Defense numbered

14 fails to articulate any basis by which a qualified privilege might bar a claim, and it fails to articulate what the “other privileges” it might be asserting could even be, let alone why they might bar any claim. Defenses numbered 18-20 provide no basis for the NPA’s assertion for why laches or a statute of limitations might be applicable; although they are affirmative defenses specifically allowed by Federal Rules, the NPA must still plead more than a bare-bones conclusory allegation, as this Court noted in *Surface Shields, Inc.*

Defense numbered 21, which states “The doctrine of unclean hands precludes Plaintiff from obtaining injunctive or other equitable relief” must also be stricken. This defense fails to meet the pleading standards of either Rules 8(a) or 9(b). It is at best a bare-bones conclusory allegation and inadequate under Rule 8. Further, it is inadequate under Rule 9(b), because a defense of unclean hands requires a defendant to “plead that [the plaintiff] acted in a way that amounts to fraud, misconduct or bad faith” and can require meeting the heightened pleading requirements of Rule 9(b). *Global Poly, Inc.*, 2004 WL 532844, at *6 (striking a “conclusory statement” that the plaintiff’s claim was barred by the doctrine of unclean hands, for failure to include particular circumstances of the representation or omission as required by Rule 9(b) (for unclean hands that amounts to fraud) and Rule 8(a)); *see Am. Top English*, 2004 WL 2271838, at *11 (“Unclean hands is an equitable defense that must be pled with the specific elements required to establish the defense.”). The NPA’s conclusory allegation does not provide the basis for its unclean hands defense to meet the requirements of Rule 8(a), let alone meet the heightened fraud pleading standards of Rule 9(b) if that basis sounds in fraud.

II. THE NPA’S IMMATERIAL, IMPERTINENT, AND SCANDALOUS ALLEGATIONS ABOUT THE FDA WARNING LETTER AND BLACK BOX WARNING SHOULD BE STRICKEN

This Court should strike the allegations in the NPA’s counterclaim concerning the warning letter sent to Morton Grove by the Food and Drug Administration (“FDA”); such

allegations are contained in paragraphs 29-34, 45, 60, 77, 88-89, 99-102, and 126, and Exhibit A. This Court should also strike the allegations concerning the black box warning on Morton Grove's Lindane medications from the NPA's counterclaim; such allegations are contained in paragraphs 3, 20-24, 26, 28, 75, 81, 87, 94, and 97. (Lists of these statements, indicating where appropriate which material in a paragraph should be stricken, are attached as Exhibit B.) The NPA included, for no discernable reason except to detract from the claims and defenses at issue and throw mud at Morton Grove, allegations about the FDA performing its proper functions and regulating the labeling and advertising for Morton Grove's prescription medications. Besides being "immaterial, impertinent, or scandalous" such that they should be stricken pursuant to Rule 12(f) of the Federal Rules of Civil Procedure, these allegations are unduly prejudicial to Morton Grove. *See Cumis Ins. Soc., Inc. v. Peters*, 983 F. Supp. 787, 798 (N.D. Ill. 1997) (noting that movant must show allegations unrelated to plaintiff's claim and unduly prejudicial).

A. *The NPA's Allegations about the FDA Letter and Black Box Warning Are Immaterial and Impertinent*

The NPA's allegations about the FDA warning letter and the black box warning on Morton Grove's Lindane medications are immaterial and impertinent. Immaterial matter is that "which has no essential or important relationship to the claim for relief or the defenses being pleaded, or a statement of unnecessary particulars in connection with and descriptive of that which is material," 5C Wright & Miller, *Fed. Practice & Procedure* § 1382. Impertinent statements are similar—they are "statements that do not pertain, and are not necessary, to the issues in question." *Id.* As an example, Wright and Miller explain how "allegations in a patent infringement action as to how the defendant gained knowledge of the invention or as to his tampering with the plaintiff's employees before the patent was issued have no bearing on the defendant's liability for infringement and are immaterial." *Id.* (describing *Anchor Hocking Glass*

Corp. v. White Cap Co., 47 F. Supp. 451 (D.C. Del. 1942)). Further, under an objective test, if proof concerning the allegations could not be introduced at trial, then the matter is immaterial and impertinent. *Id.*; see *Otero v. Vito*, 2005 WL 1429755, at *1-2 (M.D. Ga. June 15, 2005) (striking allegation about counsel's representation of defendants in prior medical malpractice action, because "any information resulting from the representation [in the previous action] is protected by the attorney-client privilege and not able to be discovered or presented at trial," and because it implied unethical conduct by defense counsel) (App. Tab 7). A motion to strike is appropriate where, as here, the allegations are "so unrelated to plaintiff's claims as to be void of merit and unworthy of any consideration." *Trustmark Life Ins. Co. v. Univ. of Chicago Hosps.*, 1996 WL 68009, at *1, 5 (N.D. Ill. Feb. 14, 1996) (striking paragraphs about unjust enrichment claim against hospital because claim barred) (App. Tab 8).

This case is not unlike *Duramed Pharmaceuticals, Inc. v. Wyeth-Ayerst Laboratories, Inc.*, No. C-1-00-735, at *9-12 (S.D. Ohio, Aug. 1, 2001) (App. Tab 9). In that case, the court struck all references in the complaint to the defendant petitioning the FDA, because none of the claims at issue could be predicated upon such conduct (due to the *Noerr-Pennington* doctrine). Here, the Court should strike all references to the warning letter and the black box warning because none of the claims at issue can be predicated upon any violations of the Federal Food, Drug, and Cosmetic Act. 21 U.S.C. § 337 (stating "proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States" or, in certain cases, by a state); *Pac. Trading Co. v. Wilson & Co.*, 547 F.2d 367, 368 (7th Cir. 1976). The only tie this material has to this case is that it concerns Morton Grove and its Lindane medications—and that alone does not give it a relationship to any claim or defense being asserted. Along the same lines, this material would be inadmissible under Federal Rule of

Evidence 403 (“Although relevant, evidence may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice . . .”). Here, it is not even relevant.

B. The NPA’s Allegations about the FDA Letter and Black Box Warning Are Scandalous

The NPA’s allegations concerning the FDA warning letter and the black box warning should also be stricken because the material is scandalous. Scandalous material “improperly casts a derogatory light on someone,” and granting motions to strike scandalous material addresses, in part, the need to avoid prejudice to a party by preventing a jury from seeing the offensive material. 5C Wright & Miller, *Fed. Practice & Procedure* § 1382. As the Seventh Circuit has noted: “Allegations may be stricken as scandalous if the matter bears no possible relation to the controversy or may cause the objecting party prejudice.” *Talbot v. Robert Matthews Distrib. Co.*, 961 F.2d 654, 664 (7th Cir. 1992); see *G-I Holdings, Inc. v. Baron & Budd*, 238 F. Supp. 2d 521, 555-56 (D.C.N.Y. 2002) (striking allegations which “harm [defendant] in the public eye and could influence prospective jury members” and which had “no bearing on” the case).

The allegations about the warning letter and the black box warning serve to cast Morton Grove and Lindane medications in a derogatory light. As a practical matter, warning letters are routine in the pharmaceutical industry—major pharmaceutical companies receive numerous warning letters each year, and the company has worked with the FDA to address all of its concerns. Likewise, a black box warning is nothing more than the FDA’s official determination about proper labeling of an approved drug. Each and every drug that has a black box warning has been determined to have benefits that outweigh the drug’s risk.

C. The NPA's Allegations about the FDA Letter and Black Box Warning Are Unduly Prejudicial to Morton Grove

The NPA's multiple allegations in its counterclaim about the warning letter from the FDA and the black box warning on Morton Grove's lindane medications are unduly prejudicial to Morton Grove. Prejudice can result when the challenged allegations "ha[ve] the effect of confusing the issues." *Cumis Ins. Soc., Inc.*, 983 F. Supp. at 798-99 (striking allegation about alter ego where plaintiff failed to state cause of action for piercing corporate veil, and allegation redundant); see *Doe v. Brimfield Grade Sch.*, 2008 WL 1722225, at *8 (C.D. Ill. Apr. 10, 2008) (striking allegations that implied claim based in part on defendant's failure to follow federal regulations as confusing and prejudicial, since claim could not be based on the regulations) (adopted magistrate recommendation) (App. Tab 10). Likewise, a party may be prejudiced by allegations if the allegations "serve to tarnish" the party. See *Moore v. Morgan Stanley & Co.*, 2007 WL 4354987, at *3 (N.D. Ill. Dec. 6, 2007) (granting defendant's motion to strike allegations of plaintiffs' attempts to settle and defendant's purportedly improper conduct after defendant argued they would "only serve to tarnish [defendant] and its counsel" and court commented they could confuse the issues) (App. Tab 11).

The NPA repeatedly mentions the FDA's letter to Morton Grove as if it is a weighty admonishment from the FDA to Morton Grove; however, it was only the beginning of a dialogue. See, e.g., *Schering-Plough Healthcare Prods., Inc. v. Schwarz Pharma, Inc.*, 2008 WL 582738, at *6 (E.D. Wis. Feb. 29, 2008) (determining FDA letters not final action because they did not follow statutory procedure necessary to withdraw drug approval based on false or misleading advertising) (App. Tab 12); *Genendo Pharm. N.V. v. Thompson*, 308 F. Supp. 2d 881, 885 (N.D. Ill. 2003) (stating that statements from agency officials below the level of Commissioner "do not rise to the level of final agency action-even when they are contained in

warning letters or other official regulatory correspondence”); *see also Lipsky v. Commonwealth United Corp.*, 551 F.2d 887, 893-94 (2d Cir. 1976) (affirming district court order to omit references in complaint to previous SEC complaint against defendant, in part because it resulted in “a consent judgment between a federal agency and a private corporation which is not the result of an actual adjudication of any of the issues”). Repeatedly mentioning the FDA warning letter only serves to cast Morton Grove in a negative light, as if the FDA was taking some final disciplinary action against Morton Grove. These allegations would undoubtedly prejudice a jury (and indeed, may prejudice the public, as the counterclaim is a public filing) against Morton Grove.

Likewise, the black box warning is the result of an FDA determination concerning proper labeling of a prescription drug product. The FDA has authority over labeling of prescription drug products, *see* 21 U.S.C. §§ 301-92 (1982), and it has determined that a “black box” warning on Lindane medications is appropriate, just as it has for hundreds of other products. Indeed, the FDA continues to support Lindane medications as second-line treatments. Yet the manner in which the NPA raises Lindane medications’ labeling is an attempt to make the product seem unsafe. That the NPA repeatedly raises the existence of the black box warning as a way to discredit Morton Grove and make its products look harmful is ground for those allegations to be stricken.

These allegations confuse the issues—the warning letter and black box warning have no relation to or bearing upon the NPA’s counterclaim, which is based entirely on Morton Grove’s political speech. Their mention in the counterclaim is a transparent ploy to get this prejudicial information before the jury. Further, the manner in which the NPA included the allegations insinuates that Morton Grove acted improperly and perhaps criminally, which is

obviously not the case. Because they are unduly prejudicial in addition to being immaterial, impertinent, and scandalous, the Court should strike these allegations from the NPA's counterclaim.

If these allegations remain, it will cause the Court to conduct a mini-trial within the trial on the collateral issue of the product's FDA-approved labeling and Morton Grove's regulatory relationship with the FDA, even though they bear no relation to the NPA's claim and no private action can even be predicated upon such FDA action. This will result in substantial expense and delay and may require, for example, the parties to retain independent FDA experts to address these issues, which are not even relevant to the claims at issue.

CONCLUSION

For the reasons listed above, this Court should strike defenses 1-22 completely; strike paragraphs 20-24, 29-34, 45, 60, 75, 77, 81, 87-89, 94, 99-102, and 126, along with Exhibit A, completely; and strike the references to the black box warning in paragraphs 3, 26, 28, and 97.

Dated: June 30, 2008

Respectfully Submitted,

MORTON GROVE PHARMACEUTICALS, INC.

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CERTIFICATE OF SERVICE

I hereby certify that on this 30th day of June 2008, I caused a copy of **Morton Grove Pharmaceuticals, Inc.'s Memorandum in Support of Its Motion to Strike Allegations and Affirmative Defenses in the National Pediculosis Association, Inc.'s Answer and Counterclaim** to be served on counsel of record via ECF electronic filing:

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